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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,145	10/06/2003	Walter C. Babcock	0003.0587/OC26122A	1094

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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	PAPER NUMBER
1616	
MAIL DATE	DELIVERY MODE
12/16/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/678,145	**Applicant(s)** BABCOCK ET AL.	
	Examiner JAMES H. ALSTRUM ACEVEDO	**Art Unit** 1616	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 December 2009 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-4,7,8,10-14 and 16-20*.
   Claim(s) withdrawn from consideration: *15*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616

12/15/09

Continuation of 11. does NOT place the application in condition for allowance because: Applicants' request for reconsideration and submission of a terminal disclaimer over copending Application No. 11/566,408 are noted. The terminal disclaimer has not yet been reviewed, thus the provisional obviousness-type double patenting rejection over copending 11/566,408 is maintained at this time. Applicants' arguments are entered.

Applicants traverse the rejection of the claims under 35 U.S.C. § 103(a) by arguing that (1) Applicants' claims do not claim substrates comprising a cross-linked polymer; (2) Gurtler does not disclose a substrate or matrix of a cross-linked polymer; (3) there is nothing in Gurtler or Jin to suggest that Gurtler's matrix polymers are equivalent to Jin's inorganic porous particle substrates; (4) the Examiner allegedly relies on Applicants' specification and impermissible hindsight to provide motivation to include PVP; (5) modification of Gurtler's teachings by Jin would render Gurler's invention unsuitable for its intended purpose; and (6) modification of Jin's teaching by removing of lipid would render Jin's invention inoperable.

The Examienr respectfully disagrees with Applicants' traversal arguments. Applicants misunderstand the basis of the rejection which is based upon the teachings of Sikorski as modified by the teachings and/or general knowledge in the prior art as set forth by Gurtler, Mulligan, Rowe, and Jin. Thus, arguments (5)-(6) are off point, because the rejection is not based upon modification of Jin's or Gutler's inventions, but rather modification of Sikorski's invention. Applicants' reply seem to ignore this aspect of the rejection and appear to misunderstand the basis of the rejection. The teachings of Gurtler and Jin establish that it was conventional in the art to utilize cellulose materials (e.g. cellulose acetate trimellitate) and inorganic materials (e.g.silica or alumina) as solid substrates onto which a pharmaceutical may be adsorbed to increase its bioavailability (i.e. through a greater solubility of the adsorbed drug). Mulligan's teaches support the notion that it was known to use an inactive polymer, such as PVP, to enhance the reat of active substance release from a solid support (e.g. cross-linked cellulose material). The observation that Applicants' specification and claims identify PVP as a dissolution-enhancing agent is not impermissible hindsight, but rather demonstrates that if the prior art suggests the inclusion of PVP, that the resulting formulation would necessarily comprise a dissolution-enhancing polymer, because "dissolution enhancement" is a property of PVP.

Regarding Rowe's teachings, Applicants indicate that they do not understand what Rowe is relied on to teach, but that if it is relied upon to teach that increased bioavailability may require less drug, Applicants agree. Applicants partly understand why Rowe was cited. Rowe was cited to support the notion that it was common knowledge in the prior art at the time of the instant invention that (a) one method to increase the bioavailability of an API is to utilize the amorphous form of the API in preference over the crystalline form of the API and (b) a necessary consequence of increasing the bioavailability of an API is that less drug would be required. Thus, Rowe establishes that it was common knowledge in the prior art that amorphous forms of drugs were advantageous vis-à-vis crystalline forms of the same drug, because the amorphous forms would generally exhibit greater solubility, bioavailability, and thus, could be used in lower amounts.

The rejections are maintained. Claims 1-4, 7-8, 10-14, and 16-20 remain rejected under 35 U.S.C. § 103(a) (see page 3 of the July 30, 2009 Final Office Action).